# Edgar Filing: ARATANA THERAPEUTICS, INC. - Form FWP

ARATANA THERAPEUTICS, INC. Form FWP January 28, 2014

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(Relating to Preliminary Prospectus dated January 28, 2014)

# **Aratana Therapeutics Announces Conditional Approval**

# of Second Canine-Specific Antibody Therapy

AT-005 Marks Aratana s First Commercial Opportunity in T-cell Canine Lymphoma

KANSAS CITY, KS, January 28, 2014 Aratana Therapeutics, Inc. (NASDAQ: PETX), a pet therapeutics company focused on the licensing or acquisition, development and commercialization of innovative biopharmaceutical products for cats, dogs and other companion animals, today announced that the United States Department of Agriculture (USDA) has granted conditional approval for AT-005, Aratana s canine-specific monoclonal antibody against CD52, which is intended as an aid in the treatment of T-cell lymphoma in dogs. AT-005 is Aratana s second Canine Lymphoma Monoclonal Antibody to receive conditional approval and it represents Aratana s first internal commercial opportunity. The company s canine B-cell lymphoma therapy, AT-004, received conditional approval from the USDA in 2012 and was licensed to Novartis Animal Health Inc. for commercialization in United States and Canada.

Aratana s canine-specific antibodies against CD20 (AT-004) for B-cell lymphoma and CD52 (AT-005) for T-cell lymphoma are directed against the same molecular targets as leading biologic drugs that are now the standard of care for treating human B-and T-cell lymphoma (Rituxan® and Campath®, respectively). The paradigm shift toward adding targeted biologic therapies for treating cancer, and the success of Rituxan and Campath in particular, serve to validate and de-risk Aratana s approach to this attractive market.

Steven St. Peter, M.D., President and Chief Executive Officer of Aratana Therapeutics, stated, We are proud to achieve our first regulatory milestone following the acquisition of Vet Therapeutics pet biologics platform, which brings us closer to market with our first internal commercial opportunity. Conditional approval by the USDA for AT-005 is also a major milestone for our dog lymphoma franchise as a whole, which we believe is poised to redefine the treatment of this important disease that affects millions of dogs worldwide. In parallel with initial commercialization of AT-005 by Aratana and AT-004 by our partner Novartis Animal Health, we are pursuing full licenses from the USDA for both products.

Genevieve Hansen, Ph.D., Head of Biologics at Aratana Therapeutics, stated, Canine lymphomas, particularly T-cell, often progress very rapidly and can become fatal within weeks if left untreated. While B-cell lymphoma occurs more frequently in today s most popular dog breeds, T-cell disease is dominant in other popular breeds, and AT-005 is the first product to be approved for treating T-cell lymphoma. Now that we have achieved conditional approvals for both AT-004 and AT-005, we are helping to bring a new standard of therapy to the full spectrum of lymphoma, which is among the most common cancers in dogs.

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These products are intended to be available to specialist veterinary practices, so pet owners should consult with their veterinarians about how to access this novel treatment option. The products will be distributed under conditional license based on USDA requirements for demonstration of safety and reasonable expectation of efficacy. Additional studies are in progress to further support the safety and efficacy of the product. Production under this license is in compliance with all regulations and standards applicable to such products.

#### **About Aratana Therapeutics**

Aratana Therapeutics is a pet therapeutics company focused on the licensing or acquisition, development and commercialization of innovative biopharmaceutical products for cats, dogs and other companion animals. Aratana believes that it can leverage the investment in the human biopharmaceutical industry to bring therapeutics to pets in a capital and time efficient manner. Aratana believes the development and commercialization of these therapeutics will permit veterinarians and pet owners to manage pets medical needs safely and effectively, resulting in longer and improved quality of life for pets.

#### Forward-Looking Statements Disclaimer

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including statements regarding our expectations regarding the approval of products; expectations regarding development programs, trials, studies, approvals and commercialization; expectations regarding in-license initiatives and partnerships; and expectations regarding the Company s plans and opportunities.

These forward-looking statements are based on management s current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: our limited operating history and expectations of losses for the foreseeable future; our lack of commercial sales; our failure to obtain any necessary additional financing; our substantial dependence on the success of certain of our lead product candidates, AT-001, AT-002, AT-003, AT-004 and AT-005; our inability to identify, license, develop and commercialize additional product candidates; our inability to obtain regulatory approval for our existing or future product candidates; the lack of commercial success of our current or future product candidates; uncertainties regarding the outcomes of studies regarding our products; our inability to realize all of the anticipated benefits of our acquisitions of Vet Therapeutics and Okapi

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Sciences; effects of competition; our failure to attract and keep senior management and key scientific personnel; our complete reliance on third-party manufacturers and third parties to conduct all our target animal studies and certain other development efforts; our lack of a sales organization; our significant costs of operating as a public company; our lack of effective internal control over financial reporting; changes in distribution channels for pet therapeutics; consolidation of our customers; impacts of generic products; unanticipated safety or efficacy concerns; our limited patents and patent rights; our failure to comply with our intellectual property license obligations; our infringement of third party patents and challenges to our patents or rights; our failure to comply with regulatory requirements; our failure to report adverse medical events related to our products; legislative or regulatory changes; the volatility of our stock price; our status as an emerging growth company, as defined in the JOBS Act; the potential for dilution if we sell shares of our common stock in future financings; the significant control over our business by our principal stockholders and management; the potential that a significant portion of our total outstanding shares could be sold into the market in the near future; effects of anti-takeover provisions in our charter documents and under Delaware law; and our intention not to pay dividends. These and other important factors discussed under the caption Risk Factors in the Company's prospectus included as part of the Registration Statement on Form S-1 filed with the Securities and Exchange Commission, or SEC, on January 28, 2014, along with our other reports filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management s estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

We have filed a registration statement (including a preliminary prospectus) with the SEC for the offering to which this communication relates. A copy of the registration statement including the preliminary prospectus can be accessed through the following link: <a href="http://www.sec.gov/Archives/edgar/data/1509190/000119312514023235/d599715ds1a.htm">http://www.sec.gov/Archives/edgar/data/1509190/000119312514023235/d599715ds1a.htm</a>. Before you invest, you should read the prospectus in that registration statement and other documents we have filed with the SEC for more complete information about us and the offering.

You may get these documents for free by visiting EDGAR on the SEC Web site at www.sec.gov. Alternatively, we, any underwriter or any dealer participating in the offering will arrange to send you the prospectus if you request it by calling Jefferies LLC at (877) 547-6340 or by emailing <a href="mailto:Prospectus Department@Jefferies.com">Prospectus Department@Jefferies.com</a>, calling Barclays Capital Inc. at 1-888-603-5847 or by emailing <a href="mailto:barclaysprospectus@broadridge.com">barclaysprospectus@broadridge.com</a> or calling William Blair & Company, L.L.C. at 1-800-621-0687 or by emailing <a href="mailto:prospectus@williamblair.com">prospectus@williamblair.com</a>.